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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,969	09/11/2003	Wael R. Joseph	19378B (27839-725)	5031
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Christopher M. Goff (27839) ARMSTRONG TEASDALE LLP ONE METROPOLITAN SQUARE SUITE 2600 ST. LOUIS, MO 63102			EXAMINER AHMED, HASAN SYED	
			ART UNIT 1615	PAPER NUMBER
			NOTIFICATION DATE 02/24/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USpatents@armstrongteasdale.com

<i>Office Action Summary</i>	Application No.	Applicant(s)	
	10/659,969	JOSEPH ET AL.	
	Examiner	Art Unit	
	HASAN S. AHMED	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2008.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8,10,12-33,35-40,42 and 44-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,10,12-33,35-40,42 and 44-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/16/08</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' amendment and remarks, filed on 29 October 2008.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-8, 10, 12-23, 25-33, 35-40, 42, 44-56, 58-61, and 62-70 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Vega, *et. al.* (U.S. Patent No. 6,153,209).

Vega, *et. al.* teach an absorbent product (see col. 1, line 7). The absorbent product disclosed is comprised of:

- the moisturizing and lubricating compositions of instant claims 1, 32, and 62 (see col. 25, line 65 – col. 26, line 14);
- the emollient of instant claims 1 and 62 (see col. 15, line 26);
- the humectant of instant claims 1, 32, and 62 (see col. 25, line 65 – col. 26, line 14);
- the immobilizing agent of instant claims 1, 32, and 62 (see col. 26, line 6);
- the compatibilizing agent (propylene glycol, butylene glycol, low molecular weight polyethylene glycol; see instant application, paragraph 0065) of instant claims 1, 32, and 62 (see col. 26, lines 5-11);

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- the vegetable oil of instant claim 2 (*see* col. 15, lines 53-54]);
- the dimethicone of instant claims 3 and 35 (*see* col. 26, line 38);
- the glycerin of instant claims 5-7 and 37-39 (*see* col. 26, line 4);
- the PEG 6000 of instant claims 1,10, 42, and 62 (*see* col. 26, line 64, incorporating U.S. Patent No. 4,556,560 by reference; col. 13, line 11 of U.S. Patent No. 4,556,560);
- the butylene glycol of instant claims 12 and 44 (*see* col. 26, line 5);
- the dispersing agent of instant claims 13 and 63 (*see* col. 20, line 27);
- the polydimethylsiloxane of instant claim 14 (*see* col. 20, line 27);
- the skin barrier enhancing agent of instant claims 16, 46, and 64 (*see* col. 17, line 66 – col. 18, line 10);
- the coconut oil of instant claims 17 and 47 (*see* col. 18, line 5);
- the antioxidant (tocopherol) of instant claims 19 and 65 (*see* col. 19, lines 25-26);
- the tocopherol of instant claims 19, 20, 49, and 50 (*see* col. 19, lines 25-26);
- the sterol derivative (cholesterol) of instant claims 21 and 66 (*see* col. 18, line 13);
- the cholesterol of instant claims 21, 22, 51, and 52 (*see* col. 18, line 13);
- the ceramide of instant claims 23, 56, and 67 (*see* col. 17, lines 29);
- the surfactant of instant claims 25, 53, and 68 (*see* col. 25, line 56);
- the diapers of instant claims 31, 61, and 69 (*see* col. 1, line 7); and
- the sorbitol of instant claim 70 (*see* col. 26, line 12).

Vega, *et. al.* explain that combining the disclosed ingredients into one absorbent product is beneficial because it provides, "...a breathable, protective barrier that keeps

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body exudates and other irritants from direct contact with the skin yet allows water vapor to pass through.” See col. 1, lines 22-27.

Vega, *et. al.* do not explicitly teach use of the dispersing agent of instant claim 34 (Dow Corning® 5329). Rather, they teach use of the dispersing agent Dow Corning® 2503 (see col. 20, line 50). Because both Dow Corning® 5329 and Dow Corning® 2503 are functionalized dimethicones (see Dow Corning® product literature), one of ordinary skill in the art would have been motivated to add either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product. There is a reasonable expectation that the addition of either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product would provide an effective dispersing agent. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either Dow Corning® 5329 or Dow Corning® 2503 to the instant absorbent product.

Vega, *et. al.* do not explicitly teach all the percentages recited in instant claims 1, 4, 8, 15, 18, 21, 32, 36, 40, 45, 48, and 51 (or the ratio recited in instant claim 33), however, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine

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experimentation.” *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

The Vega, *et. al.* reference is silent with respect to the (1) phase temperatures of instant claims 1, 28-30, 32, 58-60, and 62; (2) melting point of instant claims 26 and 54; (3) and penetration hardness of instant claims 27 and 55. Applicant’s article is the same as the prior art. It contains the same components in the same configuration. Properties are the same when the structure and composition are the same. Thus, burden shifts to applicant to show unexpected results, by declaration or otherwise. *In re Fitzgerald*, 205 USPQ 594. In the alternative, the claimed properties would have been present once the composition was employed in its intended use. *In re Best*, 195 USPQ 433.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine an emollient, a humectant, an immobilizing agent, and a compatibilizing agent into an absorbent product, as taught by Vega, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to combine these ingredients into an absorbent product because they allow for the formation of a breathable, protective barrier that keeps body exudates and other irritants from direct contact with the skin, while allowing water vapor to pass through, as explained by Vega, *et. al.*

2. Claims 1, 24, 32, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vega, *et. al.* (U.S. Patent No. 6,153,209) in view of Bowser, *et. al.* (U.S. Patent No. 5,342,976).

Vega, *et. al.* teach an absorbent product (*see above*).

The Vega, *et. al.* reference differs from the instant application in that it does not teach the glucosylceramide of instant claims 24 and 57.

Bowser, *et. al.* teach a skin composition that may be used in an absorbent product, such as a tissue wipe (*see col. 16, line 44*).

The disclosed composition contains the glucosylceramide of instant claims 24 and 57 (*see col. 1, line 67*).

Bowser, *et. al.* explain that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." *See col. 2, lines 7-9.*

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to add glucosylceramide to an absorbent product, as taught by Vega, *et. al.* in view of Bowser, *et. al.* One of ordinary skill in the art at the time the invention was made would have been motivated to this ingredient into a tissue product for the beneficial effect of enhancing skin barrier function, as explained by Bowser, *et. al.*

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 10, 12-33, 35-40, 42, and 44-69 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-59 of copending Application No. 10/659,862 ('862). Although the conflicting claims are not identical, they are not patentably distinct from each other because '862 claims a tissue product comprising a moisturizing and lubricating composition comprising an emollient, a humectant, an immobilizing agent, and a compatibilizing agent. See claim 1.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

* * * * *

Response to Arguments

Applicants' arguments filed on 29 October 2008 have been fully considered but they are not persuasive.

*

35 USC 103 over Vega, et al.

1. Applicants argue that Vega fails to recognize propylene glycol, butylene glycol, and certain low molecular weight polyethylene glycols as compatibilizing agents. See remarks, page 26.

The difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991)" Vega recognizes the need for ingredients referred to by applicants as "compatibilizing agents." Vega discloses beneficial effects of such agents, including attraction of moisture from the surrounding atmosphere to enhance water absorption of the stratum corneum (see col. 26, lines 1-2), skin protection, itch prevention, and irritation prevention (see col. 26, line 33).

2. Applicants argue that Vega's failure to disclose compounds described as "compatibilizing agents" means that a person of ordinary skill in the art would not be

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able to determine the disclosed range by routine experimentation. See remarks, pages 27-30.

Vega discloses polyethylene glycols as solvents (*see* col. 27, line 49). Examiner respectfully submits that a solvent is functionally equivalent to a compatibilizing agent, since it permits compounds (some of which may not be compatible without the solvent) to go into solution. As such, examiner respectfully submits that a person of ordinary skill in the art reading Vega would be able to determine the amount of compatibilizing agent by routine experimentation. Furthermore, the claimed range for compatibilizing agents of 1%-40% is so broad as to be obvious to a person of ordinary skill in the art in view of the teaching by Vega that appropriate amounts may be used for a composition used with an absorbent product (*see* col. 25, lines 63-64).

3. Applicants argue that Vega does not teach any advantage between higher molecular weight polyethylene glycols and lower molecular weight polyethylene glycols. See remarks, pages 31-32.

Examiner respectfully submits that Vega discloses high molecular weight polyethylene glycols by incorporating U.S. Patent No. 4,556,560 by reference at col. 26, line 64 (disclosing, e.g., PEG 6000 at col. 13, line 11). As explained above, the difference in objectives does not defeat the case for obviousness because, as MPEP § 2144 states, the "reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA

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1972) ...; In re Dillon, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991)”

4. Applicants argue that the "skin care agent" Vega refers to when incorporating U.S. Patent No. 4,556,560 is a lipase-inhibiting agent, not a high molecular weight polyethylene glycol. See remarks, page 33.

Vega describes a humectant as a “type of moisturizing emollient” (see col. 25, lines 66-67). The polyethylene glycols are described by Vega as humectants (see col. 26, lines 3-11). Vega lists “emollients” under the category of “skin care agents” (see col. 26, line 35). Thus, examiner respectfully submits that when Vega cites the '560 patent for skin care agents, polyethylene glycols are amongst the "skin care agents" Vega is referring to, according to Vega's definition of "skin care agents.”

Furthermore, the '560 teaching of using high molecular weight polyethylene glycols in an absorbent product shows that use of high molecular weight polyethylene glycols in absorbent products was well known in the art before the filing of the instant application.

5. Applicants argue that in using Vega for the teaching of polyethylene glycols as immobilizing agents, a person skilled in the art must pick and choose from "a myriad of options" and that the Office has used impermissible hindsight analysis. See remarks, pages 33-35.

Examiner respectfully submits that a person of ordinary skill in the art would have motivation to use a high molecular weight polyethylene glycol when using Vega because Vega explicitly discloses high molecular weight polyethylene glycols in

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absorbent articles by incorporating U.S. Patent No. 4,556,560 by reference at col. 26, line 64 (disclosing, e.g., PEG 6000 at col. 13, line 11). "A reference can be used for all it realistically teaches and is not limited to the disclosures in its specific examples." See *In re Van Marter* 144 uSPQ 421; *In re Windmer* 147 USPQ 518, 523; and *In re Chapman* 148 USPQ 711.

In response to applicants' argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Examiner respectfully submits that Vega's use of high molecular weight polyethylene glycols in absorbent articles by incorporating U.S. Patent No. 4,556,560 by reference at col. 26, line 64 (disclosing, e.g., PEG 6000 at col. 13, line 11) shows that use of these polyethylene glycols in absorbent articles was within the level of ordinary skill at the time the claimed invention was made.

*

35 USC 103 over Vega, et al. in view of Bowser, et al.

1. Applicants argue that a reason must exist to combine references. See remarks, page 39.

Both Vega and Bowser are in the same field of endeavor, i.e., skin compositions in absorbent products. As stated in the substantive rejection, Bowser, *et. al.* explain that a ceramide, such as glucosylceramide, is beneficial in a skin composition because, "...when applied topically to the skin, bring(s) about a marked improvement in skin condition, by enhancing skin barrier function." See col. 2, lines 7-9.

2. Applicants argue that Bowser teaches away from Vega because Vega discloses a high water content while Bowser discloses a low water content. See remarks, pages 40-41.

Examiner respectfully submits that Bowser discloses a water content as low as 15%. Vega discloses a water content as high as about 10% in the emollient alone (see col. 18, line 39). Vega teaches use of water in addition to the emollient, i.e. as an optional ingredient (see col. 25, line 56) and in water-based skin care compositions (see col. 27, line 27, and claims 24 and 28). A prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See MPEP 2144.05.

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3. Comparing the facts of *Titanium Metals* with the facts of Vega and Bowser, applicants conclude that the rule of *Titanium Metals* does not apply to Vega and Bowser. See remarks, pages 41-43.

Examiner respectfully submits that the rule of Titanium Metals, as expressed in MPEP 2144.05, is that the ranges are close enough that one skilled in the art would have expected the same properties. Bowser discloses a water content as low as 15%. Vega discloses a water content as high as about 10% in the emollient alone (see col. 18, line 39). Vega teaches use of water in addition to the emollient, i.e. as an optional ingredient (see col. 25, line 56) and in water-based skin care compositions (see col. 27, line 27, and claims 24 and 28). As such, examiner respectfully submits that a person of ordinary skill in the art would expect Bowser and Vega to have the same properties vis-à-vis water content at the low end of Bowser's disclosed range and at the high end of Vega's disclosed range.

4. Applicants argue that Vega does not disclose any of the specific humectants disclosed in new claim 70. See remarks, pages 43-44.

Examiner respectfully disagrees. Vega discloses sorbitol at col. 26, line 12.

* * * * *

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1615

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615